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UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA, ex rel. CAMPIE *et al.*,

Plaintiffs,

vs.

GILEAD SCIENCES, INC.,

Defendant.

Case No. C 11-941 EMC

NOTICE OF MOTION AND DEFENDANT'S MOTION TO DISMISS SECOND AMENDED COMPLAINT; MEMORANDUM IN SUPPORT THEREOF

Date: **May 7, 2015**
Time: **1:30 p.m.**
Courtroom: **5**
Judge: **Hon. Edward M. Chen**

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NOTICE OF MOTION AND STATEMENT OF RELIEF SOUGHT

PLEASE TAKE NOTICE that on May 7, 2015, at 1:30 p.m., pursuant to Fed. R. Civ. P. 12(b)(6), Gilead Sciences, Inc. ("Gilead") will and hereby does move the Court to dismiss Plaintiffs-Relators' Second Amended Complaint ("SAC") with prejudice. Plaintiffs-Relators Jeff and Sherilyn Campie ("Relators") have failed to plead essential elements of their claims, and their claims fail as a matter of law.

This motion is based upon this Notice of Motion and Motion, the accompanying Memorandum of Points and Authorities, all pleadings and papers on file in this matter, and such other matters as the Court may consider.

Gilead respectfully requests that this Court enter an Order dismissing the SAC with prejudice.

MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF GILEAD'S MOTION TO DISMISS SECOND AMENDED COMPLAINT

STATEMENT OF THE ISSUES TO BE DECIDED

Whether this Court should dismiss Relators' SAC for failure to state a claim upon which relief can be granted because: (1) Relators allege false statements and certifications directed only at the FDA, and not at Medicare or Medicaid as part of the payment process; (2) alleged FDA regulatory violations and "adulterated" product are not material preconditions to payment and do not give rise to False Claims Act ("FCA") liability; (3) Relators have not and cannot allege that any of Gilead's medicines is truly "worthless" as required to state a claim under the FCA; (4) Relators' state law claims fail for the same reasons their federal FCA claims fail; and (5) Relator Jeff Campie has failed to allege that he was engaged in protected activity under the FCA.

I. INTRODUCTION

Citing binding Ninth Circuit precedent, the Court's January 7, 2015 Order dismissed Relators' First Amended Complaint ("FAC") in its entirety. The Court permitted a narrow, "streamlined" amendment if Relators could allege (i) that Gilead violated any material precondition of CMS reimbursement or (ii) that any specific batch of Gilead medicine was

"worthless." Relators' 100-page SAC—their third attempt at transforming FDA manufacturing issues into an FCA case—ignores the Court's explicit order. Like the FAC, the SAC fails to state a claim and should be dismissed, this time with prejudice.

First, the SAC disregards this Court's prior ruling that, in order to survive a motion to dismiss, Relators must allege a direct, material misrepresentation to CMS, the payor agency. As the Order makes clear, the alleged false statements "made to the FDA during the approval process" were "disconnected from the request for payment" to CMS and thus could not form the basis for FCA violations. *United States ex rel. Campie v. Gilead Scis., Inc.*, No. C-11-0941 EMC, 2015 WL 106255, at *8-11 (Jan. 7, 2015 N.D. Cal.) (hereinafter, the "Dismissal Order"). Even with this third bite at the apple, Relators have still failed to identify a violation of a material precondition to payment, as the Ninth Circuit and this Court require. Dismissal is once again required for this reason alone.

Relators already have conceded that Gilead had not made any "direct misrepresentation to the payor." *See id.* at *8. Accordingly, it is not surprising that Relators' new prolix filing simply restates the same already-rejected "integrated protocols" theory of misrepresentations to the FDA that Relators alleged in prior briefs. *See, e.g.*, SAC ¶¶ 43, 49, 79, 85 (alleging that FDA regulatory compliance is "fully integrated" into various reimbursement or purchase programs). As in the now-dismissed FAC, the SAC continues to allege that Gilead made false statements and certifications to the FDA and in internal Gilead manufacturing records in order to conceal its use of active ingredient from unregistered facilities, and later in FDA applications seeking approval of those facilities.[1] The Court already rejected these fraud-on-the-FDA arguments, *see Campie*, 2015 WL 106255 at *8, and they cannot be rescued by asserting, as Relators now do, that FDA regulatory submissions are sufficiently connected to CMS

[1] *Compare* FAC ¶¶ 164, 174 *with* SAC ¶¶ 193-97 (alleging false certifications of compliance with FDA regulations in Gilead Certificates of Analysis ("COAs") and Material Status Notifications ("MSNs"); *compare* FAC ¶¶ 56-57 *with* SAC ¶¶ 162 (alleging falsified data in FDA submission for approval of Synthetics China facility); *compare* FAC Ex. C11 *with* SAC ¶ 191 (alleging false certification of Good Manufacturing Practice ("GMP") compliance in same FDA submission).

reimbursement because both agencies report ultimately to the Secretary of Health and Human Services ("HHS"). *See* SAC ¶¶ 36, 50. It is undisputed that CMS was the payor agency for the pharmaceutical reimbursement claims at issue here, and it is likewise undisputed that Relators have alleged no false statements or claims to CMS.

Nor is there any merit to the already-rejected allegations about "adulterated" medicines that used an ingredient manufactured by Synthetics China.[2] The Court rejected this theory because the alleged manufacturing deficiencies were not material preconditions to CMS reimbursement. *Campie*, 2015 WL 106255 at *12-13 ("Relators have cited no Medicare or Medicaid statute, regulation, or contractual term conditioning reimbursement on Gilead's compliance with FDA's safety or GMP regulations."). Relators now argue that products using ingredients from this one manufacturing site really were unapproved by the FDA. But as the Court already held, "there is no dispute that the [medicines] at issue in this case *were, in fact, 'approved' by the FDA.*" *Id.* at *12 (emphasis added). Relators cannot escape this holding by alleging that approved medicines somehow become unapproved medicines because of a particular alleged regulatory violation; such an allegation collides squarely with the Court's holding that the alleged regulatory violations are not material preconditions to payment. *See id.* at *13.[3]

Second, Relators have not come close to alleging an FCA "worthless" product theory under the standards set forth in the Dismissal Order and controlling law. As the Court explained previously, this is a very "narrow" theory that requires truly "worthless" product, not merely products with alleged contaminants that may be simply "worth less." *Id.* at *14 (citing *United States ex rel. Absher v. Momence Meadows Nursing Ctr., Inc.*, 764 F.3d 699, 710 (7th Cir.

[2] These same allegations were made in the FAC. *Compare* FAC ¶¶ 51-53; 161-66 *with* SAC ¶¶ 171-72; 184-86.

[3] Relators not only make many of the same allegations throughout the SAC, they also purport in a footnote to "reallege and incorporate by reference the factual allegations and the exhibits of the First Amended Complaint" ("FAC"). *See* SAC n.1. To whatever extent that this attempt to incorporate the entire now-dismissed FAC requires a response, Gilead objects and moves to strike the first footnote in the SAC.

2014)). Relators ignore the Court's ruling and fail to allege that even a single batch of Gilead's life-saving medicines was worthless—nor could they. Instead, Relators re-allege the same handful of deficiencies in Synthetics China active ingredient batches that were also identified in the FAC. *Compare* SAC ¶ 164 *with* FAC ¶ 57A. (alleged residual solvents); *compare* SAC ¶ 165 *with* FAC ¶ 57B (alleged microbes and metal contaminants); *compare* SAC ¶ 182 *with* FAC ¶¶ 156, 160 (alleged glass, cement, and paper strips). The Court already held that these alleged deficiencies do not establish that Gilead's medicines were "truly 'worthless' for the purposes for which the drugs were designed." *Campie*, 2015 WL 106255 at *14 (citation omitted). Relators have not pled any new fundamental defects that could render Gilead's medicines truly worthless.

Third, Relators' claims under state and municipal false claims statutes fail along with their federal claims. The state statutes essentially have the same elements as the federal FCA, and numerous courts have dismissed state FCA claims when the federal FCA claims fail. The SAC alleges only a few specific false certifications in applications for distribution licenses issued by Arkansas, Louisiana, Michigan, Montana, and Texas. *See* SAC ¶¶ 199-203. But these allegations of false certifications to non-payor state licensing boards had nothing to do with government reimbursement; they relate to the distribution of prescription medicines to any buyer, public or private, within the state. Thus, just like the alleged misrepresentations to the FDA for approvals, these alleged license applications are not submitted to CMS and are not material preconditions to CMS reimbursement. *See Campie*, 2015 WL 106255 at *9-11 (finding false statements to non-payor agency, disconnected from payment process, are not actionable).

Finally, Relator Jeff Campie has again failed to state a claim for employment retaliation. The Court dismissed Campie's prior employment claims because his allegations were too diffuse and generalized to show causation. *Campie*, 2015 WL 106255 at *17. Despite Campie's amendments, the SAC still fails to establish two key elements of a retaliation claim: (1) that he was engaged in protected activity (*i.e.*, investigating false claims violations), and (2) that Gilead knew of the protected activity. At most, Campie has alleged that he investigated and reported his concerns regarding various FDA regulatory issues. He does not—and indeed

cannot—plausibly allege that he raised false claims violations while employed at Gilead, as no court then or now has ever held that violations of FDA approval processes or manufacturing standards can be FCA violations. *See, e.g.*, *Campie*, 2015 WL 106255 at *8-15 (rejecting FDA regulatory violations and fraud-on-the-FDA theories as a basis for FCA liability).

Relators have now had three chances to plead viable FCA claims. For the third time, they have failed. The stale allegations in the SAC are clear evidence that any further amendment by Relators would be futile. The SAC should therefore be dismissed with prejudice.

II. PROCEDURAL HISTORY AND THE 100-PAGE SAC

A. Relators Have Failed Multiple Times to Amend Their Complaint to State a Claim After the Government Already Declined to Intervene In This Case.

Relators and former Relator Sanjay Sehgal filed their original 138-page complaint in this matter on December 5, 2011, seeking the intervention of the United States.[4] The government investigated the matter for more than a year until early 2013, at which time the Justice Department filed a Notice of Election to Decline Intervention. Relators delayed for another year before finally, on April 4, 2014, filing their 191-page FAC.

Despite its length, the FAC boiled down to a series of alleged regulatory violations by Gilead—specifically, nonconformance with pharmaceutical GMP regulations enforced by the FDA. For instance, the FAC claimed (as Relators still do in the SAC) that Gilead used active ingredients from unregistered manufacturing facilities. FAC ¶¶ 62, 65. The FAC alleged that Gilead made false statements to the FDA in order to conceal its use of the unregistered facilities and, later, in regulatory submissions seeking FDA approval of the facilities. FAC ¶¶ 70-72. The FAC also alleged that Gilead knew of a recurring impurity in an active ingredient used in many of its medicines, but concealed the matter from or failed to report it to the FDA. FAC ¶¶ 109-14. The FAC alleged several instances of product "adulteration" due to "black particles," "microbial contamination," or the presence of other particulate matter. *See, e.g.*,

[4] Former Relator Sanjay Sehgal dropped his claims and is no longer a party to the action.

FAC ¶¶ 57, 112, 160, 181, 250. The FAC asserted that these FDA regulatory issues and alleged fraud directed at the FDA led to false claims for payment from Medicare, Medicaid, and other government purchasers.

On January 7, 2015, this Court granted Gilead's motion to dismiss the FAC in its entirety. *Campie*, 2015 WL 106255 at *1. First, the Court held that alleged fraud and false statements did not create FCA liability because "the [alleged] misrepresentations at issue were to the FDA, not the payor agency (CMS) and were not made as a condition of reimbursement by CMS." *Id.* at *10. Second, the Court held that the FAC failed to plead false certifications to payors because Relators could not identify any statute, regulation, or agreement that made compliance with FDA regulations a material precondition to payment. *Id.* at *10-12. The Court also held that Relators' allegations of product defects failed to make the required showing under Ninth Circuit law that Gilead's medicines were truly "worthless." *Id.* at *14.

After dismissing the FAC, the Court permitted Relators leave to file a "streamlined" amended complaint only if they could allege a misrepresentation regarding a material precondition of payment to a payor agency, or that specific Gilead medicines purchased by the government were truly worthless. *Id.* at *15.

On February 9, 2015, Relators filed their 100-page SAC.

B. Relators Make the Same Factual Allegations Regarding Synthetics China Facilities and Products That the Court Already Rejected.

Despite the Court's specific order that Relators streamline, organize, and focus their complaint on a specific misrepresentation regarding a material precondition of payment to a payor agency, or precise worthless batches sold to the government, the SAC restates the exact same allegations of unregistered manufacturing facilities and product deficiencies at Synthetics China that were alleged in detail in the prior complaint. For example, Relators allege that Gilead used active ingredient from Synthetics China for two years before Synthetics China was registered with the FDA, *compare* SAC ¶¶ 171-72 *with* FAC ¶¶ 51-53; that Gilead falsified or concealed data from the FDA during the approval process for Synthetics China, *compare* SAC ¶¶ 162-63 *with* FAC ¶¶ 54, 56, 69-70; that one Synthetics China validation lot contained

"residual solvent levels in excess of established limits," *compare* SAC ¶ 164 *with* FAC ¶ 57A; that a second Synthetics validation lot contained "microbial contamination" and "arsenic, chromium and nickel" contaminants, *compare* SAC ¶ 165 *with* FAC ¶ 57B; that validation and other batches from Synthetics China Plant 203 contained glass, cement, paper strips, and other materials, *compare* SAC ¶¶ 182, 186 *with* FAC ¶¶ 155-56, 160; and that Gilead sieved and used the Plant 203 active ingredient in dozens of batches of finished product, *compare* SAC ¶¶ 186-87 *with* FAC ¶¶ 161-62, 166.

C. Relators Attempt to Circumvent the Court's Dismissal Order in Several Ways.

Not only does the SAC circumvent the Court's Dismissal Order by continuing to make the same factual allegations that were already dismissed, the SAC further disregards the Dismissal Order by continuing to raise the same allegations and legal theories that this Court rejected. As a factual matter, Relators continue to allege—as they did in the FAC—that Gilead made false statements to the FDA in its PAS for Synthetics China, *see* SAC ¶¶ 162-63; that Gilead falsely certified GMP compliance in the PAS, *see* SAC ¶ 191; and that Gilead made false statements and certifications in COAs, MSNs, and other internal manufacturing records, *see* SAC ¶¶ 193-97. As a legal matter, Relators also incorporate several recycled arguments and legal theories into their previously-dismissed allegations in an attempt to evade the Court's opinion and binding Ninth Circuit case law.

First, Relators present an even more farfetched version of the "integrated protocols" theory than they concocted in prior briefing, now arguing that "Medicare is administered for the Government jointly by the FDA and by [CMS], both of which are Operating Divisions of the same [] agency," HHS. SAC ¶ 36. Relators conflate the FDA and CMS by asserting that it actually is the HHS Secretary, not FDA, who by statute makes the ultimate drug approval decision. Relators also argue that the HHS Secretary, not CMS, makes certain coverage decisions. *See* SAC ¶¶ 36, 50. As made clear by the documents that Relators themselves submitted in their post-hearing supplemental briefing, as well as by the statutes, this is simply not so as a matter of law.

Second, Relators now argue a "non-approval" theory, whereby Gilead's FDA-approved products containing a Synthetics China ingredient become unapproved because the FDA is not given discretion to overlook violations of its manufacturing regulations or approval processes. *See* SAC ¶¶ 3 (arguing "no effective approval" theory); 118, 126 (arguing FDA has no discretion regarding unapproved facilities or PAS). Relators argue that because Gilead's products were not really approved, it falsely represented its products to government purchasers as approved by the FDA for safety and effectiveness. *See* SAC ¶ 247. As described below, the Court's Dismissal Order squarely rejects this theory. And Gilead's medicines remain FDA-approved.

Third, Relators enumerate various government reimbursement programs and direct purchasers in addition to Medicare and Medicaid. They argue that built into each program are conditions for participation, including that drug products are FDA-approved and that drugs comply with all FDA manufacturing regulations. *See* SAC ¶¶ 36-105. Relators cite to various regulations and policy manuals that purportedly "fully integrate" FDA approval and GMP compliance into the programs as conditions of participation and of payment. *See, e.g.*, SAC ¶¶ 40, 43 (Medicare); 48-49 (Medicaid); 53, 56-57 (TRICARE); 77, 79 (Department of Defense). As the regulations and manuals make clear, they do no such thing.

At bottom, the SAC is nothing more than a repackaged version of the FAC, raising the same factual allegations and already-dismissed legal theories. Thus, it fails to satisfy this Court's explicit requirements, as stated in the Dismissal Order. This time, the Court should dismiss the SAC with prejudice.

ARGUMENT

In considering a motion to dismiss under Rule 12(b)(6), "a court must take all allegations of material fact as true, [but] 'conclusory allegations of law and unwarranted inferences are insufficient to avoid a Rule 12(b)(6) dismissal.'" *Campie*, 2015 WL 106255 at *6 (quoting *Cousins v. Lockyer*, 568 F.3d 1063, 1067 (9th Cir. 2009)). "[C]omplaints brought under the FCA must fulfill the requirements of Rule 9(b)." *Bly-Magee v. California*, 236 F.3d 1014, 1018 (9th Cir. 2001). "To satisfy Rule 9(b), a pleading must identify 'the who, what, when, where,

and how of the misconduct charged,' as well as 'what is false or misleading about [the purportedly fraudulent] statement, and why it is false.'" *Cafasso v. Gen. Dynamics C4 Sys., Inc.*, 637 F.3d 1047, 1055 (9th Cir. 2011) (citations omitted). "[C]laims of fraud or mistake--including FCA claims--must, in addition to pleading with particularity, also plead plausible allegations." *Cafasso*, 637 F.3d at 1055.

Applying these standards, the Court should again dismiss this case, this time with prejudice. *See, e.g., In re Calpine Corp. ERISA Litig.*, No. C 03-1685 SBA, 2005 WL 3288469, at *8-11 (N.D. Cal. Dec. 5, 2005) (dismissing amended complaint with prejudice after prior dismissal order granted leave to amend only if plaintiff could allege specific, material misrepresentations; plaintiff's amended complaint failed to comply with dismissal order; and case had been pending for nearly three years).

I. THE SAC ALLEGES THE SAME FDA REGULATORY VIOLATIONS AND FRAUD-ON-THE-FDA THEORIES THAT THIS COURT ALREADY PROPERLY DISMISSED UNDER NINTH CIRCUIT LAW.

A. Relators Still Cannot Identify a Direct Misrepresentation to a Payor Agency About Reimbursement.

Like the same counts in the FAC, Counts One and Two of the SAC continue to assert FCA liability based largely on regulatory submissions to the FDA and internal Gilead manufacturing records. Large portions of the SAC repeat or closely mirror the now discredited and dismissed allegations from the FAC. For example, Relators continue to allege that Gilead made false certifications of GMP compliance in a PAS submitted to the FDA, and that Gilead made false statements and certifications in COAs and MSNs, which are internal Gilead manufacturing records. *See* SAC ¶¶ 191, 193-97. All of this, of course, was alleged previously in the FAC.[5]

[5] *Compare* FAC ¶¶ 164, 174 *with* SAC ¶¶ 193-97 (alleging false certifications of compliance with FDA regulations in Gilead Certificates of Analysis ("COAs") and Material Status Notifications ("MSNs"); *compare* FAC ¶¶ 56-57 *with* SAC ¶¶ 162 (alleging falsified data in FDA submission for approval of Synthetics China facility); *compare* FAC Ex. C11 *with* SAC ¶ 191 (alleging false certification of Good Manufacturing Practice ("GMP") compliance in same FDA submission).

These allegations fail for the same reasons as before: "[T]he [alleged] misrepresentations at issue were to the FDA, not the payor agency (CMS), and were not made as a condition of reimbursement by CMS." *Campie*, 2015 WL 106255 at *10. Relators previously conceded that there were no direct representations to CMS, *see id.* at *8, and nothing has changed.

Likewise, the allegations in the SAC regarding alleged adulterated product repeat those in the FAC and fail for the same reasons. *See United States ex rel. Rostholder v. Omnicare, Inc.*,, 745 F.3d 694, 701-02 (4th Cir. 2014) ("[O]nce a new drug has been approved by the FDA and thus qualifies for reimbursement under [federal healthcare programs], the submission of a reimbursement request for that drug cannot constitute a 'false' claim under the FCA on the sole basis that the drug has been adulterated as a result of having been processed in violation of FDA safety regulations.").[6]

B. Relators Cannot Evade the Court's Material Precondition to Payment Ruling.

Tacitly conceding the absence of an actionable misrepresentation to a payor agency, Relators make three arguments in an attempt to evade the Court's ruling and the binding Ninth Circuit cases.

First, Relators allege that the disconnected FDA regulatory violations are really connected to CMS reimbursement because both agencies report up to the HHS Secretary, who ultimately makes the coverage determination on which reimbursement is based. *See* SAC ¶ 50. This is an even more farfetched version of the previously-rejected "integrated protocols" theory, which attempted to blend together FDA approval with CMS reimbursement. Of course, the relationship between FDA approval and CMS payment does not turn on a government organization chart. Indeed, under Relators' theory, virtually every government executive function is connected since they all meet at the Office of the President. Connection to the HHS Secretary is plainly not the test. Instead, the test under Ninth Circuit law is whether the FDA

[6] *Compare* FAC ¶¶ 22-23; 42; 466-70 *with* SAC ¶¶ 129-36; 247 (alleging false certifications or false claims based on product being deemed adulterated).

representations were "a 'prerequisite to obtaining a government benefit' or the '*sine qua non* of receipt of state funding.'" *Campie*, 2015 WL 106255 at *8 (quoting *Ebeid v. Lungwitz*, 616 F.3d 993, 998 (9th Cir. 2010)).

As this Court has already held, the Ninth Circuit's material-precondition-to-payment requirement demands a "direct link" between "the alleged fraudulent conduct or statement and the request for payment." *Campie*, 2015 WL 106255 at *9. The Ninth Circuit rule is not satisfied by showing a common Cabinet Secretary, but an "entity seeking payment certif[ying] compliance with a law, rule or regulation *as part of the process through which the claim for payment is submitted*." *Ebeid*, 616 F.3d at 998 (emphasis added). Here, the SAC does not—and cannot—allege any such certifications "as part of the process through which the claim for payment [was] submitted." The FCA claims fail for this reason alone.

Second, Relators repackage the same allegations about the Synthetics China active ingredient manufacturing site into a "non-approval" theory. Just like the FAC, the SAC alleges that Gilead used active ingredient from Synthetics China for two years prior to the facility being approved by the FDA. *Compare* FAC ¶¶ 51-53 *with* SAC ¶¶ 171-72. Now, though, Relators allege that the medicines containing Synthetics ingredient were not really approved by the FDA because somehow the FDA was barred from overlooking these regulatory violations. *See, e.g.*, SAC ¶¶ 3, 118, 126. But the medicines—including Truvada®, Emtriva®, and Atripla®—were FDA-approved during the entire period, as the Court explicitly found. *Campie*, 2015 WL 106255 at *12. FDA-approved medicines do not become unapproved merely because a GMP violation occurred, even taking Relators' allegations of the regulatory violation as true. Otherwise, every regulatory violation—including the failure to obtain site validation—would become an FCA violation. That is exactly what this Court and others have held is *not* the law. *See Campie*, 2015 WL 106255 at *13 (quoting *Omnicare*, 745 F.3d at 702) ("[R]elator's allegations of regulatory violations fail to support FCA liability."). Indeed, as this Court has recognized, there are many "complexities, subtleties and variabilities" in the FDA approval process. *Campie*, 2015 WL 106255 at *11. "[S]ubstantial policy concerns" would arise if the

Court were to become enmeshed in second-guessing which regulatory violations were so significant as to impact or somehow rescind the actual approval of medicines. *Id.*

Third, Relators allege different reimbursement programs and government purchasers of Gilead's medicines, but none of these programs contain material preconditions to payment or reimbursement that advance Relators' FCA theory.[7] As with the government programs alleged previously, Relators fail to identify *any* statute, regulation, or agreement that conditions payment by any of these government reimbursement programs and direct purchasers on compliance with FDA regulations. Relators cite to statutes, regulations, and Memoranda of Understanding ("MOU") relating to these programs, but *none* requires compliance with manufacturing regulations as a material precondition to payment. *See, e.g.*, SAC ¶ 55 (describing FDA-approval requirement for TRICARE); ¶ 62 (describing FEHBP formulary being tied to FDA approval); ¶¶ 77-78 (describing DOD MOU that defers to FDA approval of drugs); ¶ 83 (describing VA MOU that defers to FDA approval of drugs).

Under *Ebeid*, *Hendow*, and this Court's ruling, the absence of any statute, regulation, or agreement that conditions reimbursement on compliance with FDA regulations is fatal. *See Ebeid*, 616 F.3d at 1000 (finding false certification only where statute expressly conditions payment on compliance with specific law); *United States ex rel. Hendow v. Univ. of Phx.*, 461 F.3d 1166, 1175-76 (9th Cir. 2006) (finding condition of payment where the "statute, regulation, and agreement [] all explicitly condition[ed]" payment on compliance); *Campie*, 2015 WL 106255 at *10 ("Relators here have not pointed to any law, regulation, or contract provision that conditions CMS's payment on Gilead's compliance with [GMPs].").

In its Dismissal Order, the Court correctly found that Medicare and Medicaid reimbursement is conditioned "only on FDA approval of the drugs sold. [And h]ere, Gilead had

[7] *See, e.g.*, SAC ¶¶ 53-59 (describing TRICARE program and coverage of FDA-approved drugs); ¶¶ 60-65 (describing Federal Employee Health Benefits Program ("FEHBP") and coverage of FDA-approved drugs); ¶¶ 76-81 (describing Department of Defense ("DOD") purchases and coverage of FDA-approved drugs); ¶¶ 82-87 (describing Department of Veterans Affairs ("VA") purchases and coverage of FDA-approved drugs); ¶¶ 93-100 (describing PEPFAR purchases and coverage of products subject to "accepted quality standards").

obtained FDA approval of all the drugs in question." *Campie*, 2015 WL 106255 at *10; *accord Omnicare*, 745 F.3d at 701-02. Nothing in the SAC changes this. As this Court recognized, any government payor certainly "could require a pharmaceutical manufacturer to certify, for example, its continued adherence to FDA safety and GMP regulations as part of the payment process." *Campie*, 2015 WL 106255 at *13. But the government reimbursement and direct purchase programs at issue here have not done so. Final dismissal is therefore mandated.

II. RELATORS FAIL TO ALLEGE THAT EVEN A SINGLE BATCH OF GILEAD'S MEDICINES WAS WORTHLESS.

The Court granted a narrow leave to replead and specifically identify "worthless" batches of Gilead's medicines. *Campie*, 2015 WL 106255 at *15. As the Court explained, citing Ninth Circuit law, this theory is applied very narrowly and requires Relators to plead that Gilead's products are completely "worthless," not just defective or "worth less." *Id.* at *14 (quoting *Absher*, 764 F.3d at 710); *see also United States ex rel. Lee v. SmithKline Beecham, Inc.*, 245 F.3d 1048, 1053 (9th Cir. 2001); *United States ex rel. Ruhe v. Masimo Corp.*, 977 F. Supp. 2d 981, 996 (C.D. Cal. 2013) (requiring showing of "no medical value"). Citing these cases, the Court specifically held in the Dismissal Order that product defects such as microbial contamination; presence of charred particles; failed potency and purity testing; "glass, cement and fibrous materials" contamination; and presence of "visible black particles" and Teflon, all were insufficient to show that product was truly worthless under the law. *Campie*, 2015 WL 106255 at *14 (citing FAC ¶¶ 57, 110, 113, 124-25, 160, 180, 184-85).

Perhaps because even Relators recognize that Gilead's life-saving medicines have great value, the SAC contains no new allegations that could lead the Court to a different conclusion than it already reached on the "worthless services" theory. In fact, the SAC does not even allege that a single batch of Synthetics China or Gilead product was "worthless." Nor does the SAC allege that any of Gilead's medicines had "no medical value" or were the equivalent of providing nothing to patients or government payors. For this reason alone, Relators' attempt to rely on a "worthless services" theory of FCA liability fails.

Furthermore, Relators allege very few even potential defects in only a few batches of active ingredient. Relators allege that one Synthetics China validation batch contained "residual solvent levels in excess of established limits" and "other impurities." SAC ¶ 164. They allege that another Synthetics validation batch contained "microbial contamination" and that the batch was "contaminated with . . . arsenic, chromium, and nickel." SAC ¶ 165. They allege that Synthetics China Plant 203 validation batches contained contaminants including "colored glass, cement, and fibrous building materials." SAC ¶ 182. Relators also allege that a separate Plant 203 validation batch was "contaminated by 'brown paper strips' and pinkish-orange particles,' the latter of which was described only as 'unidentified organic material.'" SAC ¶ 182. And Relators generally allege that Gilead finished goods batches using product from Synthetics China were similarly contaminated or contained impurities but sieved for use. *See* SAC ¶¶ 178-79; 185-86. But these are the same alleged defects that Relators alleged in the FAC, and the Court already has ruled that these are insufficient to state a claim for worthless services. *See Campie*, 2015 WL 106255 at *14 (listing product defect allegations from FAC).

Finally, Relators contend that Gilead's alleged GMP noncompliance resulted in "adulterated" medicines that were "essentially contraband" and "subject to seizure" by the government. *See* SAC ¶¶ 135, 152. But as this Court held, medicines can be deemed technically "adulterated" for any number of reasons, many of which have nothing to do with actual defects, much less with a medicine having literally no medical value. *See Campie*, 2015 WL 106255 at *11 n.5 (noting that a "drug can be adulterated for any number of reasons").[8] Relators' allegations of "adulterated" medicines are wholly insufficient to show that any such medicines were truly worthless, as the law requires.

[8] Relators' assertions to the contrary are also contradicted by the FDA's guidance regarding products not manufactured in accordance with GMPs. *See Facts About the Current Good Manufacturing Practices (CGMPs)*, U.S. FOOD & DRUG ADMIN. (Jan. 6, 2015), http://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/ucm169105.htm ("If a company is not complying with CGMP regulations . . . [i]t does not mean that there is necessarily something wrong with the drug. For consumers currently taking medicines from a company that was not following CGMPs, FDA usually advises these consumers not to interrupt their drug therapy.").

Relators have not alleged that any batch of Gilead's life-saving medicines was truly worthless—nor can they. They cannot use the FCA as a fishing expedition for discovery into the Synthetics China batches at issue when they have not even alleged the elements of a viable FCA claim (*i.e.*, that any product was "worthless").[9] Their allegations of defective product and related FCA claims should be dismissed with prejudice.

III. RELATORS' STATE LAW CLAIMS FAIL ALONG WITH THEIR FEDERAL CLAIMS.

In Counts Three through Twenty-Eight of the SAC, Relators again allege copycat violations of numerous state and municipal false claims laws. These state law claims fail along with Relators' FCA claims and likewise should be dismissed with prejudice.

Courts have found that, in general, state false claims statutes contain language very similar to the FCA and require the same elements to state a claim. *See, e.g.*, *United State ex rel. Ge v. Takeda Pharm. Co.*, No. CIV.A. 10-11043-FDS, 2012 WL 5398564 (D. Mass. Nov. 1, 2012), *aff'd*, 737 F.3d 116 (1st Cir. 2013) ("With respect to the state FCA claims, the issue is whether claims submitted to state Medicaid programs misrepresented compliance with a material precondition to payment."); *United States ex rel. Pervez v. Beth Israel Med. Ctr.*, 736 F. Supp. 2d 804, 816 (S.D.N.Y. 2010) (New York false claim statute requires same four elements as federal FCA, so state claims dismissed "for the same reasons").[10] For this reason,

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[9] *See Rutman Wine Co. v. E. & J. Gallo Winery*, 829 F.2d 729, 738 (9th Cir. 1987) ("[I]f the allegations of the complaint fail to establish the requisite elements of the cause of action, our requiring costly and time consuming discovery and trial work would represent an abdication of our judicial responsibility." (citation and internal quotation marks omitted)).

[10] *See also United States ex rel. Dalitz v. AmSurg Corp.*, 2014 U.S. Dist. LEXIS 177374, at *13 (E.D. Cal. Dec. 23, 2014) (noting that the California FCA contains language similar to federal FCA); *United States ex rel. Rector v. Bon Secours Richmond Health Corp.*, No. 3:11-CV-38, 2014 WL 1493568, at *11, 14 (E.D. Va. Apr. 14, 2014) ("[The] Complaint fails to meet the requisite element of materiality because the certification upon which [Relator] seeks to base his claims is insufficient. . . . Because the VFATA and FCA are analogous and Relator incorporates all of his arguments into both causes of action, Relator's VFATA claims will be dismissed for the very same reasons that his FCA claims fail."); *United States v. Bollinger Shipyards, Inc.*, No. CIV.A. 12-920, 2013 WL 393037, at *10 (E.D. La. Jan. 30, 2013) ("Under both Louisiana and Federal common law, the fraud standard is similar to the standard for FCA claims under 3[1] U.S.C. §§ 3729(a)(1)(A)-(B). To make out either claim, a plaintiff must show that the defendant made a ***material*** false representation with scienter and that the plaintiff relied on it." (emphasis added)); *Cade v. Progressive Cmty. Healthcare, Inc.*, No. 1:09–cv–3522–WSD, 2011 (continued…)

courts often analyze state false claims allegations under the established standards applied to a claim under the federal FCA.[11] This includes Rule 9(b)'s specificity requirements, which apply to state-law false claims allegations. *See, e.g.*, *Kearns v. Ford Motor Co.*, 567 F.3d 1120, 1125 (9th Cir. 2009) (holding that Rule 9(b) applies to state-law causes of action "alleging fraud [or] facts that necessarily constitute fraud"); *United States ex rel. Mooney v. Americare, Inc.*, No. 06–CV–1806 (FB)(VVP), 2013 WL 1346022, at *2 (E.D.N.Y Apr. 3, 2013) (finding that Rule 9(b) applies to New York FCA claims); *Cnty. of Santa Clara v. Astra United States, Inc.*, 428 F. Supp. 2d 1029, 1036 (N.D. Cal. 2006) (applying Rule 9(b) to California FCA claims).

Like the prior complaint, the SAC cites in conclusory fashion to the state statutes at the end of the allegations and relies on the same factual allegations underlying the federal claims. Relators' state claims thus fail for the same reasons that the federal claims fail. In addition, Relators cannot rely on generalized pleadings and must allege with specificity the false claims submitted to each state at issue. *See, e.g.*, *United States ex rel. Nowak v. Medtronic, Inc.*, 806 F.

WL 2837648, at *3 (N.D. Ga. July 14, 2011) (noting that the Georgia False Medicaid Claims Act uses "nearly identical language" to the federal FCA); *United States v. Bon Secours Cottage Health Servs.*, 665 F. Supp. 2d 782, 783 n.2 (E.D. Mich. 2008) ("The Michigan Medicaid False Claims Act is substantially similar to the FCA."); *Ortho-McNeil-Janssen Pharms., Inc. v. State*, 432 S.W.3d 563, 571 (Ark. 2014) ("[A] person is held liable to the state of Arkansas if he or she knowingly makes a false statement or representation of a ***material*** fact with respect to information required pursuant to applicable federal and state law, rules, regulations, and provider agreements." (emphasis added)); *Int'l Game Tech., Inc. v. Second Judicial Dist. Ct.*, 127 P.3d 1088, 1101 (Nev. 2006) ("Nevada's FCA was expressly modeled after the federal FCA.").

[11] *See, e.g.*, *United States ex rel. Williams v. McKesson Corp.*, No. 3:12-CV-0371-B, 2014 WL 3353247, at *4 (N.D. Tex. July 9, 2014) (evaluating Texas Medicaid Fraud Prevention Act claims "under the FCA's well-defined legal requirements"); *United States ex rel. Schubert v. All Children's Health Sys., Inc.*, 2013 U.S. Dist. LEXIS 163075, 22, 2013 WL 6054803, at *18, 22 n.8 (M.D. Fla. Nov. 15, 2013) ("Conclusions as to the federal F[CA] apply equally to the Florida F[CA] because the Florida version mirrors the federal F[CA]."); *United States ex rel. Kennedy v. Aventis Pharms., Inc.*, 512 F. Supp. 2d 1158, 1163 n.2 (N.D. Ill. 2007) ("Case law regarding the FCA is also applicable to the IWRPA."); *State ex rel. Seiden v. Utica First Ins. Co.*, 96 A.D.3d 67, 71 (N.Y. 2012) ("The NYFCA follows the federal F[CA. A]nd therefore it is appropriate to look toward federal law when interpreting the New York act."); *Lewis v. City of Alexandria*, 756 S.E.2d 465, 469 n.4 (Va. 2014) ("The VFATA is based on the federal civil [FCA]. . . . The FCA cases thus provide guidance for our review in this appeal."); *State ex rel. Grayson v. Pac. Bell Tel. Co.*, 142 Cal. App. 4th 741, 746 n.3 (2006) ("Given the 'very close similarity of California's [FCA] to the federal [FCA], it is appropriate to turn to federal cases for guidance in interpreting the [California] act.'" (citations omitted)).

Supp. 2d 310, 357 (D. Mass. 2011) ("[Relators] must allege some specificity with respect to each asserted state and cannot rely upon generalized pleadings . . . . [But relator] fails to identify any specific fraudulent or false claim submitted to any state."). Relators have failed to plead with the required specificity for most of the state FCA claims at issue.

For only a handful of states, Relators now cite statements allegedly made to non-payor state licensing boards in applications for pharmaceutical distribution licenses. *See* SAC ¶¶ 198-203 (alleging certifications in license applications in Arkansas, Louisiana, Michigan, Montana, and Texas). But even assuming that Gilead applied for such licenses, the certifications at issue are not actionable under the FCA because they are made to non-payor state licensing boards, not Medicaid, and are completely disconnected from the payment process. *See Campie*, WL 106255 at *10 (false claims must be "for payment" to be actionable). Once again, Relators have alleged no statute, regulation, or agreement that makes these certifications a material precondition to CMS reimbursement. *See id.* at *12 (discussing failure of similar certifications in applications to the FDA to create subsequent implied false claims for CMS payment).

Finally, Relators' state FCA claims rely on the same speculative allegations—that agencies approving the distribution of Gilead's medicines were duped and should or would not have granted the approvals—that the Court has already rightfully rejected in this case. *Campie*, 2015 WL 106255 at *11. In dismissing similar allegations that the FDA should or would not have approved Gilead's products in the first place, the Court noted that this type of claim requires a "Court sitting on an FCA case . . . to delve deeply into the complexities, subtleties and variabilities of the FDA approval process." *Id.* The Court found that the judiciary is "ill-equipped" to predict what the FDA would have done, or second-guess what the agency actually did, in order to determine materiality under the FCA. *See id.* The same practical and institutional problems arise out of Relators' allegations that state licensing boards would not have issued licenses or would have withdrawn those licenses. For the same reasons, the Court should decline the invitation to predict how more than two dozen separate state licensing boards would have responded to Relators' allegations.

Dismissal of Relators' state FCA claims with prejudice is appropriate for any and all of the foregoing reasons. In the alternative, if the Court does not dismiss on the merits any individual state law claim set forth in Counts Three through Twenty-Eight, then there is no reason for the Court to retain jurisdiction over that state law claim. Countless FCA courts have refused to exercise supplemental jurisdiction and dismissed state law claims where the federal claims fail.[12]

IV. RELATOR JEFF CAMPIE HAS AGAIN FAILED TO ALLEGE UNLAWFUL EMPLOYMENT RETALIATION.

Jeff Campie again alleges unlawful retaliation and termination in violation of the FCA, California Labor Code ("CLC") sections 98.6 and 1102.5, and California public policy. *See* SAC ¶¶ 415-31. To state a claim for unlawful retaliation, Campie must allege (1) that he was engaged in protected conduct (here, investigation of false claims as opposed to mere GMP regulatory issues); (2) that his employer knew or could have known that he was complaining about false claims, as opposed to investigating regulatory GMP issues pursuant to his job responsibilities; and (3) that there was a causal connection between any adverse employment action and Campie's investigation of false claims. *See Cafasso*, 637 F.3d at 1060 (describing tripartite test for FCA retaliation); *Turner v. City and Cnty. of S.F.*, No. C-11-1427 EMC, 2012

[12] *E.g.*, *United States ex rel. Heath v. AT & T, Inc.*, No. 11-CV-1897 (RJL), 2014 WL 2584191, at *4 (D.D.C. June 10, 2014) ("The complaint brings no other federal claims, and I decline to exercise jurisdiction over the remaining state and local law claims."); *Sears v. Hous. Auth.*, No. 11-CV-1876-LHK, 2014 WL 1369594, at *15 (N.D. Cal. Apr. 7, 2014) ("Sears' FCA claim is the only claim that presents a federal question. Having granted summary judgment on that claim . . . the balance of factors points toward declining to exercise jurisdiction over Sears' remaining claims, which are all based on state law . . . ."); *United States ex rel. Marquis v. Northrop Grumman Corp.*, No. 09 C 7704, 2013 WL 951095, at *4 (N.D. Ill. Mar. 12, 2013) ("Having resolved the federal claims in this case . . . the court declines to exercise supplemental jurisdiction over the remaining state law claim."); *United States ex rel. Piacentile v. Sanofi Synthelabo, Inc.*, No. CIV.A. 05-2927 KSH, 2010 WL 5466043, at *10 (D.N.J. Dec. 30, 2010) ("With [the] federal claims dismissed, the only remaining claims are those brought under the various state false claims acts. The Court declines to exercise jurisdiction as to those claims."); *Sierotowicz v. N.Y.C. Hous. Auth.*, No. 04-CV-3148 NGG/LB, 2009 WL 2382314, at *2 (E.D.N.Y. July 31, 2009) ("To the extent Plaintiffs maintain claims under . . . the False Claims Act, those claims are dismissed . . . . The court declines to exercise supplemental jurisdiction over any pendent state law claims.").

WL 6631490, at *12 (N.D. Cal. Dec. 19, 2012) (analyzing California False Claims Act retaliation claims under three-part test applied to federal FCA retaliation).

The Court dismissed Campie's previous FCA retaliation claims for failing to show any causal connection between his activities and alleged termination. *See Campie*, 2015 WL 106255 at *17. The Court expressly reserved judgment on whether Campie was engaged in any protected activity because he had "indicated that he can provide further factual allegations on th[at] point" in an amended complaint. *Id.* Campie now alleges various meetings and other instances between January 2009 and July 2009 where he complained of FDA regulatory violations at Gilead. *See, e.g.*, SAC ¶¶ 223-41. But these allegations still fail to establish two key elements of a retaliation claim: (1) that he was investigating actual false claims for payment, and (2) that Gilead had notice of any such protected activity prior to any alleged adverse employment action.

A. Investigating Alleged FDA Regulatory Noncompliance Does Not Constitute Protected Activity Under the FCA.

Ninth Circuit law is clear that reporting mere regulatory violations does not constitute protected activity under the FCA. *See United States ex rel. Hopper v. Anton*, 91 F.3d 1261, 1269 (9th Cir. 1996) (affirming summary judgment where relator was "merely attempting to get [a] School District to comply with Federal and State regulations" and the "investigatory activity did not have any nexus to the FCA"); *Turner*, 2012 WL 6631490, at *12-13 (finding that California FCA retaliation claim failed where the plaintiff alleged no facts showing reasonable belief in conduct that constitutes an actual false claim, as opposed to mere violations of a municipal charter).

In *Hopper*, the relator claimed that she had been retaliated against for reporting dozens of times, both internally and to the California Department of Education, that her employer, a school district, was not complying with state and federal regulations governing evaluation of potential special education students. *See* 91 F.3d at 1263-64. In reviewing Hopper's retaliation claims, the Ninth Circuit found that the evidence showed "Hopper was merely attempting to get the School District to comply with Federal and State regulations. . . . She was not trying to

recover money for the government[.] She was not investigating fraud. She was not whistleblowing as envisioned in the paradigm *qui tam* FCA action." *Id.* at 1269 (citation omitted). Similarly, Campie's allegations demonstrate that he was merely investigating and trying to influence Gilead management regarding various FDA regulatory compliance matters. *See, e.g.,* SAC ¶ 226 (alleged complaint regarding degraded product later referenced in FDA warning letter); ¶ 228 (alleged "explicit[] complain[t] that Gilead was violating FDA regulations"); ¶ 230 (alleged reporting on falsified data in FDA submission and threat that if the conduct did not stop, Campie would "inform the FDA"). Campie clearly viewed these as FDA regulatory matters, which is what they were.

Campie now—self-servingly and in his third complaint—alleges that years ago, he believed "Gilead was defrauding the Government and the States by knowingly seeking payment for contaminated drugs, first without obtaining required governmental approval and later based on falsified test results, false certifications, and falsified PAS documents." SAC ¶ 218. To begin, Campie never alleges that he made this allegation at the time. And in any event, the allegation is legally untenable, as no court has ever held that these alleged violations of FDA manufacturing regulations and approval processes can constitute false claims. In fact, this Court affirmatively held that they cannot. *Campie*, 2015 WL 106255 at *8-15 (rejecting FDA regulatory violations and fraud-on-the-FDA theories as a basis for FCA liability). Campie had no basis when employed at Gilead, nor can he have any today, to believe that the alleged FDA regulatory violations that he investigated were false claims. In short, Campie was not engaged in protected activity under the FCA.

B. Gilead Could Not Have Known that Campie Was Investigating Actual False Claims, Especially When Campie's Job Was to Investigate the Alleged FDA Regulatory Violations at Issue.

Under these circumstances, Gilead no more than Campie himself could have understood that Campie's reporting on FDA regulatory matters somehow was an investigation of false claims for payment. *See Campie*, 2015 WL 106255 at *8-15 (rejecting FDA regulatory violations and fraud-on-the-FDA theories as a basis for FCA liability). This is particularly true where, as here, it was the employee's job to investigate and internally report on the alleged FDA

regulatory matters at issue. *United States ex rel. Ramseyer v. Century Healthcare Corp.*, 90 F.3d 1514, 1523 (10th Cir. 1996) (dismissing FCA retaliation claims where "the monitoring and reporting activities described in plaintiff's complaint were exactly those activities plaintiff was required to undertake in fulfillment of her job duties"); *United States ex rel. Bartlett v. Tyrone Hosp., Inc.*, 234 F.R.D. 113, 129 (W.D. Pa. 2006) ("[I]nvestigatory actions of non-compliance pursuant to one's duty as an employee do not constitute protected conduct.").

Campie now alleges that Gilead was aware that his actions constituted "protected activity" because former Relator Sanjay Sehgal also complained to management about inadequate FDA approvals prior to the release of product. *See* SAC ¶ 236. But Mr. Sehgal—who long ago abandoned the attempt to transform FDA regulatory issues into false claims violations and dropped his claims in this case—also was reporting on matters of regulatory compliance and not false claims for payment. Campie now also alleges that Gilead knew of his protected activity because he was presented with a severance agreement that allegedly released FCA claims against the company. *See* SAC ¶ 240. But generalized or boilerplate releases encompassing a litany of claims against a former employer are utterly inadequate to show notice of false claims activity, particularly when this Court has ruled that Campie's FDA regulatory concerns have no link to false claims for payment. *Campie*, 2015 WL 106255 at *8-15.

C. Campie's State Law Retaliation Claims Also Should Be Dismissed.

For similar reasons, Campie has failed to state a claim for retaliation in violation of CLC section 98.6, as shown by *Muniz v. United Parcel Service, Inc.*, 731 F. Supp. 2d 961 (N.D. Cal. 2010). In *Muniz*, the court began its analysis of retaliation based on California public policy and CLC sections 98.6 and 1102.5 by noting that to establish a prima facie case of retaliation a plaintiff must show "(1) she engaged in a protected activity, (2) her employer subjected her to an adverse employment action, and (3) there is a causal link between the two." 731 F. Supp. 2d at 969 (citation and internal quotation marks omitted). Although whistleblowing may in certain cases be a protected activity under CLC section 98.6, the court found that the plaintiff could not maintain the action when internally "reporting [the regulatory] violations [at issue] w[as] part of her job duties." *See id.* at 969-70. Like that case, Campie's allegations of internally reporting

alleged GMP violations merely suggest that he was raising issues pursuant to his job duties as "Senior Director of Global Quality Assurance" at Gilead. *See* SAC ¶ 13.

Campie's claim of retaliation in violation of California public policy is also legally defective because reporting violations of a statute, such as the federal Food, Drug, and Cosmetic Act ("FDCA"), that "establishes a specific procedure and forum for addressing a violation" cannot serve as the basis for such an action. *See Dutra v. Mercy Med. Ctr. Mt. Shasta*, 209 Cal. App. 4th 750, 756 (2012) (stating that extending a common law cause of action under such circumstances would "impermissibly give [a plaintiff/employee] broader remedies and procedures than that provided by the statute" at issue); *Takeda Pharm. Co.*, 2012 WL 5398564 at *5-6 (noting that FDA procedures allow private "citizens to petition FDA to bring action against specific violators" of the FDCA).

Furthermore, because all of Relators' federal claims under the FCA fail and warrant dismissal, there is no reason for this Court to retain jurisdiction over any of Campie's state law employment claims. *Coyaso v. Bradley Pac. Aviation, Inc.*, 578 Fed. App'x 715, 717 (9th Cir. 2014) ("[I]n the usual case in which all federal-law claims are eliminated before trial, the balance of factors . . . will point toward declining to exercise jurisdiction over the remaining state-law claims.") (citations and internal quotation marks omitted); *Steshenko v. Gayrard*, No.: 13–CV–03400–LHK, 2014 WL 2120837, at *11-12 (N.D. Cal. May 20, 2014) (quoting the same language as the *Coyaso* Court and dismissing state law claims after refusing to exercise supplemental jurisdiction). These state law employment claims should be dismissed accordingly.

CONCLUSION

For the reasons set forth above, Gilead respectfully requests that this Court dismiss Relators' SAC and all Counts therein with prejudice.

Respectfully submitted,

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